IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	JAPUNTICH, DANIEL A.		
Application No.:	08/240877	Group Art Unit:	3761
Filed:	May 11, 1994	Examiner:	Aaron J. Lewis
Title:	FILTERING FACE MASK THAT HAS A NEW EXHALATION VALVE		

REPLY BRIEF

Commissioner for Patents
Washington, DC 20231

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January 30, 2003
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Signed by: Susan M. Dacko

Dear Sir:

This Reply Brief is submitted under 37 CFR § 1.193(b)(1). Copies of the Exhibits can be found in the Appeal Brief mailed May 31, 2002.

Each of the following statements made in the Examiner's Answer are responded to by applicants as follows.

1. Examiner's Answer, ¶ bridging pp. 4 and 5.

"McKim (figs. 1 and 5) teaches a flap retaining surface (14a) and a seal surface being nonaligned and positioned relative to each other to allow for a cross-sectional curvature of at least one free portion of the flexible flap when viewed from the side in closed position, the nonalignment and relative positioning of the flap-retaining surface and the seal surface also allowing for the one free portion of the flexible flap to be pressed against the seal surface for the purpose of seating quickly and effectively without float or bounce after each opening (col. 1, lines 64-72)."

Applicants' Response:

The Examiner is incorrect in stating that McKim teaches a flexible flap. In finding that McKim's valve reed qualifies as a flexible flap, the Examiner has either misinterpreted the scope and content of the McKim patent or has unreasonably interpreted the meaning of applicants' term "flexible flap". Applicants have defined the term "flexible flap" to mean that "the flap can

deform or bend in the form of a self-supporting arc when secured at one end as a cantilever and viewed from a side elevation (see e.g., FIG. 5)".[1] The context under which this definition is cast pertains to flaps that bend in response to gravity and the force from a wearer's exhalate. McKim does not teach or suggest such a structure. Instead, McKim describes a valve reed 14 that is made of spring sheet material such as shim stock.[2] A valve reed of the McKim construction cannot deform or bend in the form of an arc when supported as a cantilever and exposed to the force of gravity.[3] Robert Betts, an expert in 2-cycle engines, explains this:

> Since 1965, the 2-cycle engines that I have either constructed or worked on have used a reed valve of varying degrees of stiffness. None of the reed valves that I have encountered, however, were "flexible" as the term has been defined in the above-captioned patent application and recited in paragraph 4 above. Reed valves that are used on 2-cycle engines can bend when exposed to a force such as shown in Fig. 3 of the McKim patent. The reed valves, however, are not so flexible that they will bend in the form of a self-supporting arc when secured at one end as a cantilever. Reed valves do not bend in the form of such an arc in response to the mere force of gravity. If the [2-cycle engine intake] valves were constructed to have that degree of flexibility, the 2-cycle engines in which they were used would surely not be operative. If secured at one end as a cantilever and having a free end that projects from the point of securement, a reed valve would project in an essentially straight line when viewed from a side elevation. The degree of stiffness that reed valves possess are orders of magnitude greater than the flexible flaps that are used on exhalation valves.[4]

In view this evidence, the record unequivocally shows that reed valves are not capable of being bent in response to gravity. Such valves accordingly also would not respond to the force of mere exhalation pressure from a wearer's breath. Any interpretation of the McKim patent, which interpretation would have the McKim valve be so flimsy, would not be consistent with the McKim valve's utility. As explained by Betts, "If the [2-cycle engine intake] valves were constructed to have that degree of flexibility, the 2-cycle engines in which they were used would surely not be operative." And any interpretation of

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[1] See, Applicants' specification at p. 7, lines 22-25.
[2] See, McKim at col. 1, lines 59-63.
[3] Although the definition set forth on p. 7, lines 22-25 does not explicitly use the word "gravity" in defining "flexible", it is clear, however, from the specification, the supporting Figures, and the prosecution history, that no other definition is intended by applicants. Accordingly, to eliminate any issue that might possibly exist in this regard, the Examiner is granted the full authority to make explicit what some might say is implicit by amending the definition, as follows, using an Examiner's amendment: "the flap can deform or bend in the form of a self-supporting arc when secured at one end as a cantilever, exposed to gravity, and viewed from a side elevation (see FIG. 6).
[4] See Exhibit E attached to Appeal Brief mailed May 31, 2002.

applicants' term "flexible flap", which interpretation would be so broad as to encompass sheet metal stock, would not be consistent with applicants' invention and the terms that they use to describe it. Shim stock that is used as the valve reed in a 2-cycle engine is not be suitable for use as a dynamic element in an exhalation valve. The Betts declaration explains that valve reeds "are on orders of magnitude greater than flexible flaps that are used on exhalation valves." The Examiner is reminded that claims are to be given not simply their broadest construction possible but rather their broadest "**reasonable** interpretation", construction, or meaning "**consistent** with the specification".[5] Accordingly, applicants respectfully request that the expression "flexible flap" be construed in light of the specification as it would be *reasonably* interpreted and understood by one of ordinary skill the art.

2. Examiner's Answer, p. 5, 1st full ¶.

"It would have been obvious to modify the flexible flap and seat of Simpson et al. (Fig. 2) to be curved because it would have provided for quick effective seating without float or bounce after each opening as taught by McKim (col. 1, lines 64-72)."

Applicants Response:

This statement is erroneous because it relies on the erroneous premise that "quick effective seating without float or bounce" is a desired goal in the design of exhalation valves. Applicants have furnished the record with uncontroverted evidence that "float or bounce" is not a problem that is encountered in the exhalation valve art. Applicants accordingly are entirely perplexed by the Examiner's insistence on disregarding this evidence of record in favor of relying on a totally unsupported proposition. In the Supplemental Appeal Brief mailed September 19, 2002, applicants made the following argument, which argument and supporting facts appear to have been wholly ignored by the Examiner:

> Although not necessary to overcome the rejection, appellants have nonetheless responded to this unsupported position by furnishing testimony of an expert in the field of exhalation valves, John Bowers. Bowers stated that "under the airflows and pressure drops that are encountered in the filtering face mask, 'bounce or float' is not an occurring event or problem that investigators in the exhalation valve art need to deal with." Thus, although the motivation recited in the September

[5] *In re Reuter*, 651 F.2d 751, 756 (CCPA 1981); *see also, In re Sneed*, 710 F.2d 1544, 1548 (Fed. Cir. 1983) ("Claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.").

> 10, 2001 Office Action for combining the two references does not exist, the Examiner, in the most recent Office Action mailed February 26, 2002, has totally ignored the evidence of record in the Bowers Affidavit and continues to state that "[i]t would have been obvious to modify the flexible flap and seat of Simpson et al. (fig. 2) to be curved because it would have provided for quick effective seating without float or bounce after each opening as taught by McKim (column 1, lines 64-72)." The Examiner's refusal to cite any prior art source in support of this view is clear legal error. The Federal Circuit has explained at length in *In re Lee* that obviousness rejections based on combinations of references are improper when there is no evidence within the four corners of the record, to support the reasoning behind making the combination. Conclusory statements simply are not evidence.

The Examiner has yet to explain why a person of ordinary skill in exhalation valve art would have been motivated to modify an exhalation valve to eliminate float or bounce *when exhalation valves do not exhibit this problem.* Despite ample opportunity to do so, the Examiner also has not cited a single reference to support his position that "float or bounce" was a problem in the exhalation valve art. In view of the lack of any cogent explanation, in conjunction with the lack of any properly supporting evidence to back the above position, the rejection under 35 U.S.C. § 103, based on a combination of Simpson and McKim, cannot properly be sustained.

3. Examiner's Answer at the p. 5, 2nd to last ¶.

"As to claims 79, the exhalation valve (12) of Simpson et al. as modified by McKim is disclosed as opening responsive to a wearer's exhalation, it is fully capable performing of recited function of permitting the exit of any amount of exhale gasses which exceed the cracking pressure of the valve including greater than 50 % of the entering airflow when airflow exceeds 30 liters per minute under normal exhalation test.

Applicants' Response:

This position is the result of a pure hindsight reading of applicants' specification. Only through reading applicants' specification could anyone select the teachings from these two manifestly different disclosures and arrive at any conclusion regarding the percentage of exhaled air that would pass through the valve. Nowhere does Simpson or McKim provide any indication of the amount of exhale gasses that would pass through such a modified exhalation valve under a normal exhalation by a person. Applicants' specification is the only document that provides such supporting data. Applicants have provided the public with disseminating evidence of the amount of exhaled air that passes through their valve. In the working examples of the present specification,

the applicants demonstrated that they were able to remove so much air (>100%!) from the mask interior during a simulated exhalation, that an influx of cool ambient air occurred during the exhalations. For filtering face masks that have porous mask bodies, this was an amazing achievement because it demonstrated, for the first time, that a filtering face mask could operate as a cool-air aspirator — drawing cool, low humidity, air into the mask interior through the filter media to substantially improve wearer comfort (see Examples 7-13). No prior art exhalation valve on a filtering face mask had yet to demonstrate such a feat during an exhalation. Thus, only through a reading of applicants' specification would a person of ordinary skill have any idea of the % total flow that would pass through the valve. All of the work undertaken to set up these experiments, carry them out, calculate the results, and submit them for publication cannot be so easily discounted. This certainly is one of the reasons why applicants are entitled to a patent on their creation of a filtering face mask that has a new exhalation valve.

4. Examiner's Answer at ¶ bridging pp. 11-12.

"Appellants' argument that McKim constitutes nonanalogous art [is wrong] because it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. In this case, is submitted that one of ordinary skill would look to the art of valves (which includes McKim ('618) to address problems associative with the effectiveness of valve seating of a valve element which is used for controlling the direction of flow of breathable air through such a valve. McKim clearly addresses the problem effectiveness of valve seating by non-aligning the flap retaining service and the seal service relative to each other thereby providing effective seating without float or bounce after each opening (col. 1, lines 64-72)."

Applicants' Response:

Ironically, it is not applicants' argument that is not accurate, but rather the Examiner's incorrect reading of the facts and his incorrect application of the law. The Examiner's position is thus erroneous for two reasons. Firstly, the record does not reflect any evidence of a desire to provide "effective seating without float or bounce after each opening" of an exhalation valve. As applicants have demonstrated repeatedly during this prosecution, the Examiner's position is merely a statement of his opinion, wholly unsupported by any evidence of record. Nowhere does

the record show that "float or bounce" is a problem that needs to be overcome in the exhalation valve art. In fact, the evidence of record establishes the exact opposite: it shows that "float or bounce" is not a problem that needs to be dealt with by persons who design exhalation valves. Secondly, the second part of the two-part test for determining whether a reference is analogous does not look only at the purpose of the device described in the cited reference. The test looks at the purpose of **both** the claimed invention and the device described in the prior art document, and it compares these two purposes.[6] The Examiner has not made such a comparison and therefore has committed legal error by only examining the purpose of McKim.

Since the Examiner does not contest whether McKim satisfies part (1) of the 2-part test for evaluating whether a reference is analogous, we only need to examine this issue under part (2).

In the leading case that deals with "analogousness" under part (2) of the test, the Federal Circuit has explained that the USPTO needs to consider the purposes of the reference disclosure *and* the invention in determining whether a reference is reasonably pertinent to the particular problem that confronted the inventor.[7] In *In re Clay*, the Federal Circuit found the cited reference to be not analogous when (1) the prior art taught the use of a gel within a natural, underground, oil-bearing formation to channel flow in a desired direction and (2) the applicant, Clay, had invented the use of a gel to fill the confined dead volume of a man-made storage tank. Although the inventor Clay and the prior art (Sydansk) both described technology that related to the use of gels in the petroleum industry, *the prior art Sydansk reference was found to be nonanalogous because the purpose of the Sydansk teachings were different from the purpose of the Clay invention.* Sydansk was faced with the problem of recovering oil from rock, which was not pertinent to the problem with which Clay was involved, namely, preventing loss of stored product in a tank's dead volume. The court also recognized that the subterranean formation of

[6] Because the Examiner does not dispute the fact that McKim does not reside in applicants' field of endeavor, we only need to evaluate McKim under part (2) of the test.

[7] *In re Clay*, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. **Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.** If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his intention. **If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it** (emphasis added)")

Sydansk was not structurally similar to and did not operate under the same temperature and pressure and did not function like Clay's storage tanks.[8]

As in *In re Clay*, the McKim reference also does not have the same purpose as applicants' invention, it does not operate under the same temperature and pressure, and it does not function like the claimed invention. Float or bounce was a problem that occurred when 2-cycle engines operated at high rpms (10,000 to 12,000 rpms). It has not been a problem that occurs in exhalation valves, which open and close in cadence with a person's breathing, about 20 to 60 cycles per minute. In addition, internal combustion engines operate at extraordinarily higher temperatures and pressures than a person's exhalation breath and are not powered by a person's lungs but by gasoline combustion. Finally, McKim's valve is used for intake into a combustion cylinder while the present valve is used for exhaust from the interior gas space of a mask.

Applicants accordingly encourage the Examiner (and the Board if the rejection is still to be maintained) to carefully consider the *In re Clay* decision in light of the present rejection.[9] A summary of the facts in *In re Clay* are provided below for ease of reference:

[8] *See, Clay*, 23 USPQ2d at 1601 ("Moreover, the subterranean formation of Sydansk is not structurally similar to, does not operate under the same temperature and pressure as, and does not function like Clay's storage tanks.").

[9] *See also, SRI Int'l, Inc. v. Advanced Tech. Lab.*, 45 F.3d 443, 445 (Fed. Cir. 1995) ("The problem Green solved was how to compensate for changes in the spectral distribution of the return ultrasonic signal, with time or depth of penetration into a living organ, for enhanced image resolution and/or signal to noise ratio. The Minton reference, which relates to seismic prospecting circa 1946, almost thirty years prior to Green's filing date, would not have logically commended itself to Green's attention in considering how to compensate for changes in the spectral distribution of a received ultrasonic signal in an object such as a body part."); *In re Green*, 22 F.3d 1104, 1105 (Fed. Cir. 1994) ("A person of ordinary skill in the aircraft vane art simply would not find a 1919 reference about broken blades in a pugging mill reasonably pertinent to this problem."); *In re Butera*, 1 F.3d 1252, 1253, 28 USPQ2d 1399, 1400 (Fed. Cir. 1993) ("Butera's design is for air fresheners and insect repellents, while Hodge's is for metal ball anodes. The design of Hodge involves a different type of article from Butera's design and it is not analogous. One designing a combined insect repellent and air freshener would therefore not have reason to know of or look to a design for a metal ball anode. Since Hodge is not analogous, the Board clearly erred in finding Hodge to be citable as prior art. Therefore there was no basis for rejecting Butera's claimed design as obvious."); *Wang Laboratories, Inc. v. Toshiba Corp.*, 993 F.2d 858, 864, 26 USPQ2d 1767, 177_ (Fed. Cir. 1993) ("Wang's SIMMs were designed to provide compact computer memory with minimum size, low cost, easy repairability, and easy expandability. In contrast, the Allen-Bradley patent relates to a memory circuit for a larger, more costly industrial controller. SRAMs were used by Allen-Bradley because of their intended industrial environment. According to Dr. Frey, size was not a consideration in the Allen-Bradley work. Thus, there is substantial evidence in the record to support a finding that the Allen-Bradley prior art is not reasonably pertinent and is not analogous.").

In re Clay	**Result: reference <u>not</u> analogous**					
	Description	***Problem to be Solved***	***Purpose***	***Operating Conditions***	***Similarities***	***Differences***
Clay	use of gel to displace liquid product from tank dead volume	preventing loss of stored product to tank dead volume	to displace liquid product from dead tank volume	• subterranean rock • high temps (115°C) and bore pressures	both used in petroleum industry	different purposes and operating under different temperatures and pressures
Prior Art Sydansk	use of gel to fill anomalies in natural oil-bearing conditions	recovering oil from rock	to channel flow in a desired direction	• made storage tank • ambient temp and pressure		
In re Japuntich et al.	**Result: not yet decided**					
Applicants' Invention	use of a new flapper-style exhalation valve in a filtering face mask	keeping valve closed under any orientation while allowing low pressure drop during an exhalation	to allow valve to open easier during an exhalation but remain closed under neutral conditions	• exhale valve on face mask body • body temperatures • low pressures • cadence of person's breathing	both relate to valves	different purposes and operating under different temperatures, pressures, and speeds
McKim	use of new reed intake valve in a two-stroke engine	stopping flutter or bounce of reed valve while operating under high RPM conditions	to eliminate float or bounce of valve reed to improve power and efficiency of engine	• intake valve on 2-cycle engine • high temps • high pressure • high speeds (10-12,000 rpms)		

The Federal Circuit has stated that when the reference "is directed to a different purpose [than the applicants' invention], the inventor would accordingly have less motivation or occasion to consider it" and therefore it would not be analogous.[10] Because the Examiner only considered the purpose of McKim's valve in evaluating whether it was analogous but did not consider the purpose of applicants' invention and compare it with McKim's purpose, the Examiner has erred in determining that McKim is analogous. This error, in turn, has caused the Section 103 rejection to be improperly maintained.

[10] *Id.*

5. Examiner's Answer at p. 12, 1st full ¶.

"Appellants' argument that the valve of McKim lacks the required flexibility of applicant's invention is disagreed with because McKim (figs. 1 and 3) illustrates flexibility of the valve flap (14)."

Applicants' Response:

McKim may illustrate in its figs. 1 and 3 that its valve reed can be bent, but this illustration does not mean that the reed valve 14 in McKim qualifies as a "flexible flap" as that term would be reasonably interpreted by a person of ordinary skill consistent with a reading of applicants' specification. As explained above, any interpretation of McKim that would have its valve reed 14 qualify as a flexible flap would either be the result of an incorrect reading of the scope and content of McKim or an overbroad unreasonable interpretation of the term "flexible flap". The record shows that McKim's valve reed 14 "of sheet material, such as, for example, shim stock" would not be able to bend in response to gravity or breath from a person. Unless the Examiner can supply the record with evidence to demonstrate otherwise, it would appear that the Examiner is giving unreasonable breadth to the meaning of "flexible flap".

In footnote 3 above, applicants have proposed an Examiner's Amendment that should put this issue to rest. If the Examiner does not wish to make such an amendment, then the Board should interpret the term in a reasonable manner consistent with the specification. To the extent that the Board feels that applicants' proposed amendment would have a bearing on whether applicants' claims may be allowed, applicants encourage the Board to exercise their authority under 37 CFR § 1.196(c) and suggest the proposed amendment or any variation thereof.

6. Examiner's Answer at p. 12, 1st full ¶.

"Further, the manner of bending illustrated in figs. 1 and 3 of McKim is consistent with appellants definition of a ...the flap can form or bend in the form of a self-supporting arc when secured at one end as a cantilever and view from a side elevation...'."

Applicants' Response:

The manner of bending McKim's metal valve reed is not consistent with applicants' definition. As indicated above, applicants define flexible flaps that can deform or bend in response to gravity or pressure from a person's exhaled breath. McKim clearly uses a mechanical means to cause its valve reed 14 to be bent. The force that McKim uses, as described by Betts, is

on orders of magnitude greater than the forces that are used to bend flexible flaps in exhalation valves. When the meaning of applicants' term "flexible flap" is given an interpretation that is not just the broadest construction possible but is instead the broadest *reasonable* interpretation, *consistent* with the specification, (and further when McKim's scope and content is properly interpreted, particularly in light of the Betts explanation), there can be no other conclusion other than that McKim's valve reed 14 would not qualify as a flexible flap.

7. Examiner's Answer at ¶ bridging pages 12-13.

"Appellants' assertion that the record is devoid of any teaching, suggestion or motivation to combine the prior art to Simpson et al. and McKim is not accurate. As set forth in the body of the rejection, the reason for combination of Simpson et al. with McKim is because it would have provided for quick effective seating without float or bounce after each opening as taught by McKim (col. 1, lines 64-72)."

Applicants' Response:

In taking this position, the Examiner confuses unsupported opinion with evidence. As applicants have stated on numerous occasions, persons skilled in the art of designing exhalation valve's do not search for solutions to eliminating float or bounce. Applicants have supported these statements with uncontroverted documentary evidence in the form of Affidavits and Declarations signed by persons skilled in the field of designing such valves. Because applicants have fully established that persons who design exhalation valves do not encounter — much less look for solutions to — "float or bounce" problems, the record lacks any motivating evidence for making the combination asserted in the present rejection. The Examiner has not yet cited a single reference that states, either explicitly or implicitly, that exhalation valves exhibit float or bounce problems. Nonetheless, the Examiner continues to assert that person skilled in the art of designing exhalation valves would have used the teachings of McKim's gasoline engine reed valve for purposes of eliminating float or bounce in an exhalation valve. The Examiner, therefore, is using a basis for maintaining the combination that has no basis or evidentiary authority in the record, other than perhaps the Examiner's own unsupported opinion.[11] Bald

[11] "Unsupported" is probably not the best word to use in this sentence. The Examiner's view is not merely "unsupported": it is actually "false". This falsity has been established by Bowers and Fabin when they unequivocally stated that float or bounce is not a problem that is confronted by persons who design exhalation valves.

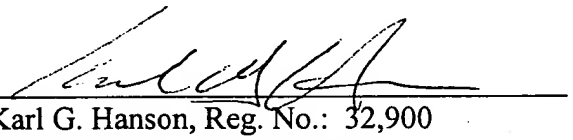
conclusions like this, however, are not *evidence* that can be properly relied on to sustain a rejection based on a combination of references.[12]

CONCLUSION

Applicants believe that they have fully refuted the positions taken by the Examiner in maintaining the present obviousness rejection. Barring a withdrawal of the rejection by the Examiner in response to the consideration of this Brief, applicants respectfully request that the Board reverse the decision below.

Respectfully submitted,

January 29, 2003
Date

By: 
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[12] *See, In re Dembiczak*, 50 USPQ 1614, 1617 (Fed. Cir. 1999) ("Broad conclusory statements regarding the teachings of multiple references, standing alone, are not 'evidence'."); *See also, Lee*, 61 USPQ2d at 1434 ("With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that 'the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software' and that 'another motivation' would be that the automatic demonstration mode is user friendly and it functions as a 'tutorial' do not adequately address the issue of motivation to combine. The factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority.").